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Appl. No. 09/271,411
Amdt. dated August 1, 2007
Reply to ISPAI decision of June 28, 2007

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Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1-44. (canceled)

45. (Currently amended) A device for analyzing a sample, the device comprising:
- a) a body having:
 - i) a reaction chamber for conducting a reaction;
 - ii) a separation channel for separating sample components;
 - iii) a transition region connecting the reaction chamber to the separation channel, wherein the portion of the body defining the transition region has sufficiently low thermal conduction so that the transition region substantially thermally isolates the reaction chamber from the separation channel; and
 - iv) at least one valve in the transition region for controlling fluid flow between the reaction chamber and the separation channel; and
 - b) at least two electrodes coupled to the body, the electrodes being positioned to induce electrophoretic flow, electroosmotic flow, or isoelectric focusing of the sample components in the separation channel when a voltage difference is applied between the electrodes, wherein the electrodes are screen-printed on the body.
46. (Previously presented) In combination with the device of claim 45, an instrument into which the device may be inserted, the instrument having electrical connections for applying the voltage difference between the electrodes and having at least one light source and detector for detecting the sample components in the separation channel.
47. (Previously presented) The combination of claim 46, wherein the instrument further includes a heater for heating the reaction chamber.

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48. (Previously presented) The combination of claim 46, wherein the instrument includes additional optics for monitoring the reaction chamber.
49. (Previously presented) The device of claim 45, wherein the body further includes:
 - a) a side channel connected to the transition region for adding or removing fluid from the transition region; and
 - b) at least a second valve for controlling fluid flow through the side channel.
50. (Previously presented) In combination with the device of claim 49, an instrument into which the device may be inserted, wherein the valves comprise membrane valves, the instrument has electrical connections for applying the voltage difference between the electrodes, and the instrument further has means for controlling the membrane valves.
51. (Previously presented) The combination of claim 50, wherein the instrument pneumatically controls the membrane valves.
52. (Previously presented) The device of claim 45, wherein the valve comprises a mechanical valve having an open position and a closed position.
53. (Previously presented) The device of claim 45, wherein the body further includes an inlet port for adding the sample and reagents to the reaction chamber.
54. (Previously presented) The device of claim 45, wherein the body comprises a one-piece polymeric body having the reaction chamber, transition region, and separation channel formed therein.
55. (previously amended) The device of claim 45, wherein the separation channel comprises an electrophoresis or isoelectric focusing channel containing separation material.
56. (Canceled).
57. (Previously presented) The device of claim 45, wherein each of the electrodes is embedded in the body such that one end of the electrode protrudes through an external

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surface of the body and such that the other end of the electrode protrudes into an internal region of the body.

58. (Previously presented) The device of claim 45, wherein the body comprises a polymeric material, and wherein the electrodes are over-molded in the body.
59. (Canceled)
60. (Currently amended) A method for analyzing a sample, the method comprising the steps of:
- a) introducing the sample into a device having:
 - i) a reaction chamber;
 - ii) a separation region;
 - iii) a transition region connecting the reaction chamber to the separation region, wherein the transition region has sufficiently low thermal conduction so that the transition region substantially thermally isolates the reaction chamber from the separation region; and
 - iv) at least one valve in the transition region;
 - b) subjecting the sample to a reaction in the reaction chamber while the valve is closed, wherein the transition region substantially thermally isolates the reaction chamber from the separation region during the reaction;
 - c) optically monitoring reaction products contained in the reaction chamber~~opening the valve~~;
 - d) determining if sufficient reaction products have been generated within the reaction chamber prior to injecting a sample plug into the separation region~~injecting into the separation region a sample plug containing reaction products~~;
 - e) opening the valve;
 - f) injecting into the separation region the sample plug containing reaction products;
 - e-g) separating the reaction products in the separation region; and

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~~f.h)~~ detecting the separated reaction products.

61. (Canceled)
62. (Previously presented) The method of claim 60, wherein the reaction comprises a nucleic acid amplification reaction, and wherein the reaction products comprise amplified nucleic acid.
63. (Previously presented) The method of claim 60, wherein the plug is injected into the separation region by electrophoretic injection.
64. (Previously presented) The method of claim 60, wherein:
- i) the device includes a body defining the reaction chamber, separation region, and transition region, and wherein the separation region comprises a separation channel;
 - ii) the device further includes at least two electrodes coupled to the body, the electrodes being positioned to induce electrophoretic flow, electroosmotic flow, or isoelectric focusing of the reaction products in the separation channel when a voltage difference is applied between the electrodes;
 - iii) the method further comprises the step of inserting the device into an instrument having electrical connections for applying the voltage difference between the electrodes and having at least one light source and detector for detecting the reaction products in the separation channel; and
 - iv) the steps of separating and detecting the reaction products comprise applying the voltage difference through the electrical connections in the instrument and detecting the reaction products using the at least one light source and detector.
65. (Previously presented) The method of claim 64, wherein the instrument further includes a heater for heating the reaction chamber, and wherein the step of subjecting the sample to the reaction comprises heating the reaction chamber with the heater.

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66. (Previously presented) The method of claim 60, wherein:
- i) the device further includes a side channel connected to the transition region; and
 - ii) the method further comprises the step of adding fluid to or removing fluid from the transition region through the side channel prior to, during, or after the step of injecting the sample plug into the separation region.
67. (Previously presented) The method of claim 60, wherein:
- i) the device further includes a side channel connected to the transition region; and
 - ii) the method further comprises the steps of adding reagents to the transition region through the side channel and mixing the reaction products with the reagents in the transition region prior to the step of injecting the sample plug into the separation region.
68. (Previously presented) The method of claim 60, wherein:
- i) the device further includes a side channel connected to the transition region; and
 - ii) the method further comprises the steps of adding buffer solution to the transition region through the side channel and injecting the buffer solution into the separation region prior to the step of injecting the sample plug into the separation region.
69. (Previously presented) The method of claim 66, wherein the device further includes at least a second valve for controlling fluid flow through the side channel, and wherein the method further comprises the step of opening and closing the second valve to control fluid flow through the side channel.
70. (Previously presented) The method of claim 60, wherein the reaction products are separated by electrophoresis.
71. (Currently amended) AThe method for analyzing a sample, the method comprising the steps of: of claim 60, wherein the reaction products are separated by isoelectric focusing

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- a) introducing the sample into a device having:
 - i) a reaction chamber;
 - ii) a separation region;
 - iii) a transition region connecting the reaction chamber to the separation region, wherein the transition region has sufficiently low thermal conduction so that the transition region substantially thermally isolates the reaction chamber from the separation region; and
 - iv) at least one valve in the transition region;
- b) subjecting the sample to a reaction in the reaction chamber while the valve is closed, wherein the transition region substantially thermally isolates the reaction chamber from the separation region during the reaction;
- c) opening the valve;
- d) injecting into the separation region a sample plug containing reaction products;
- e) separating the reaction products in the separation region, wherein the reaction products are separated by isoelectric focusing; and
- f) detecting the separated reaction products.